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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,939	03/04/2008	Alan Barrett	UTSG:260US	1637

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,939	BARRETT ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,9,12,13,19-23,26-32,41 and 43* is/are pending in the application.

4a) Of the above claim(s) *1,4,6,9,12,13,19,20,41 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group II, claims 21-23 and 26-32 is acknowledged and entered. Since Applicant did not indicate whether the restriction was made with or without traverse, and no arguments were presented against the restriction requirement, the Office will treat the election as an election without traverse. Claims 1, 4, 6, 9, 12, 13, 19-23, 26-32, 41 and 43 are pending. Claims 1, 4, 6, 9, 12, 13, 19, 20, 41 and 43 are withdrawn from consideration being drawn to non-elected subject matter. Claims 21-23 and 26-32 are under examination.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

3. The drawings are objected to because they recite sequences for which there are no reference sequence identifiers. In lieu of filing new drawings, Applicant may amend the specification to include the sequence identifiers for the drawings that recite sequences. Correction is required.

Claims Summary

4. The claims are drawn to a composition comprising an isolated West Nile virus (WNV) serocomplex virus envelope protein domain III polypeptide. (The term "serocomplex virus" is

referencing the fact that WNV is a member of the Japanese encephalitis serocomplex of the genus Flavivirus.) The polypeptide is derived from WNV strain 382-99, EthAn4766, 385-99, Kunijin MRM16, Golblum, TL443, DakAnMg798 or 804994.

Specifically, the WNV envelope protein domain III polypeptide comprises an amino acid sequence at least 80% or at least 95% identical to SEQ ID NO: 11. More specifically, the polypeptide comprises amino acids 292 to 402 of SEQ ID NO: 3, or an amino acid sequence set forth in SEQ ID NO: 11. The polypeptide is linked to a substrate such as a microtiter plate, bead or microarray.

In another embodiment, the composition containing the polypeptide is a vaccine which may comprise an adjuvant. Also claimed is a kit comprising a suitable container means and the WNV envelope protein domain III polypeptide. The intended use of the kit is to screen for antibodies.

Priority

5. The embodiments of claims 21, 30 and 31 are entitled to benefit of priority of USSN 60/403,893, filed August 16, 2002. The embodiments of claims 22, 23, 26-29 and 32 are entitled to the benefit of priority of USSN 600/445,581, filed February 6, 2003.

Claim Objections

6. Claims 22 and 27 are objected to for the following minor informalities:

- Claim 22 is objected to because it does not have a period at the end of the sentence.
- Claim 27 is objected to because the phrase "an amino acid sequence set forth in SEQ ID NO: 11" may refer to the entire sequence or a fragment of the sequence. If Applicant intends to encompass fragments of SEQ ID NO: 11, no amendment need

be made. However, if Applicant intends to encompass the full-length sequence and not fragments, suggested language is "the amino acid sequence set forth in SEQ ID NO: 11" (emphasis added). Clarification is requested.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites, "wherein the West Nile virus envelope protein domain III polypeptide is derived from" a variety of strains. The term "derived from" indicates that the polypeptide may be taken as is from the strain, or modified in some manner from the form present in the strain. If the polypeptide is modified from the original, one cannot determine what regions are retained from the original without further definition/clarification.

Claims 26 and 27 depend (directly and indirectly, respectively) on cancelled claim 25. In order to further prosecution, the Office has treated the claims as if they depend (directly and indirectly, respectively) from claim 23.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 30 and 31 are directed to vaccine compositions comprising WNV envelope domain III polypeptide and an adjuvant, respectively. The specification is not enabling for vaccine compositions that protect against WNV challenge comprising domain III polypeptides with or without an adjuvant.

The breadth of the claims encompasses a composition that is capable of inducing protective immunity against WNV challenge. The nature of the invention is a vaccine that elicits a protective immune response against viral challenge.

The state of the art with regard to WNV vaccines for humans is that there is no vaccine. Dauphin *et al.* (*Vaccine*, 2007, 25:5563-5576, "Dauphin") reviews the vaccine candidates that have been tested or are being tested, none of which have been shown to efficacious in humans. Table 1 of the Dauphin reference lists the different vaccine candidates, one of which is a truncated E protein proven protective in mice and horses, but not evaluated in humans (see page 5571). The other vaccine candidate constructs in Table 1 are structurally distinct from the instantly claimed polypeptide construct: inactivated or attenuated whole virus, prM/E proteins and DNA, canarypox and lentivirus vectors. More specifically, Chu *et al.* (*Journal of Immunology*, 2007, 178:2699-2705, "Chu") discloses the immunization of mice with WNV envelope domain III protein with and without CpG-DNA adjuvant (see abstract). Chu found that WNV envelope domain III protein in combination with CpG adjuvant generated a protective immune response in mice. Chu suggests that the protein in combination with the CpG adjuvant

may be a potential subunit vaccine against WNV (abstract and page 2704, second column). While Dauphin and Chu acknowledge vaccine candidates for WNV that have either similar or the same construct as is instantly claimed, the art is not predictable with regard to the protective effects in animals being predictive of the human response. In other words, protection in mice and horses is not predictive of protection in humans upon WNV challenge.

Applicant's specification does not provide any working examples of challenge experiments in an acceptable animal model of human WNV infection/disease. Given the breadth of the claims, the state of the art, the unpredictability in the art, and the lack of working examples in the specification, it would require undue experimentation to use the claimed compositions as human vaccines.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22, 23 and 26-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Chang (US Patent Applicant Publication 2003/0022849 A1, published January 30, 2003). Note that the embodiments of claims 22, 23, 26-29 and 32 are entitled to the benefit of priority of USSN 600/445,581, filed February 6, 2003.

The claims are summarized above. Chang discloses polypeptides comprising the E protein of flaviviruses, such as WNV (see [0031-0032]). (The E protein naturally contains domain III.) Chang teaches that the polypeptide can be conjugated to a carrier molecule that facilitates its attachment to a solid phase (see [0033]). The polypeptide can be bound to an ELISA 96-well plate or bead, for example (see [0100-0101]).

Chang also discloses immunogenic compositions comprising the polypeptide in combination with an adjuvant (see [0085]). Chang's SEQ ID NO: 16 of 692 amino acids contains a region that is an exact match for the instant SEQ ID NO: 11 full-length sequence.

With regard to claim 22 which requires that the polypeptide be derived from one of the strains recited, the Chang patent does not specifically name those strains. However, the source of the domain III polypeptide need not be those strains because the polypeptide is "derived from" those strains. Since the derivation process may involve modification from the original strain's polypeptide, Chang's polypeptide qualifies as a polypeptide derivative of those strains. Therefore, the claimed embodiments are anticipated by Chang.

10. Claims 21-23 and 26-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang (US Patent 7,227,011 B2). The claims are summarized above. Chang discloses polypeptides comprising the E protein of flaviviruses, such as WNV (see columns 6 and 8). (The E protein naturally contains domain III.) Chang teaches that the polypeptide can be conjugated to a carrier molecule that facilitates its attachment to a solid phase (see column 8, lines 29-31). The polypeptide can be bound to an ELISA 96-well plate or bead, for example (column 20, lines 8-13 and 29-35).

Chang also discloses immunogenic compositions comprising the polypeptide in combination with an adjuvant (col. 17, beginning at line 29). Chang's SEQ ID NO: 16 of 692 amino acids contains a region that is an exact match for the instant SEQ ID NO: 11 full-length sequence.

With regard to claim 22 which requires that the polypeptide be derived from one of the strains recited, the Chang patent does not specifically name those strains. However, the source of the domain III polypeptide need not be those strains because the polypeptide is "derived from" those strains. Since the derivation process may involve modification from the original strain's polypeptide, Chang's polypeptide qualifies as a polypeptide derivative of those strains. Therefore, the claimed embodiments are anticipated by Chang.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (US Patent Applicant Publication 2003/0022849 A1, published January 30, 2003) or Chang (US Patent 7,227,011 B2 in view of Degroot *et al.* (WO 02/083903 A2, published October 24, 2002 "Degroot"). Claim 32 is directed to a kit for screening antibodies, comprising a suitable container means and WNV domain III polypeptide. Neither of Chang specifically suggest the packaging of the WNV polypeptide into a kit. However, Chang does suggest the use of the polypeptide in diagnostic assays such as ELISAs to detect antibodies (column 20, lines 8-13 of the Chang patent, and paragraph [0100] of the PGPUB). It would have been obvious to package Chang's polypeptide into a kit for an ELISA or any other immunoassay that uses the polypeptide because it is routine in the art to make kits. It would have been obvious to include a suitable container means in order to preserve the integrity of the polypeptide. Degroot teaches the packaging of WNV antibodies into a kit for detecting WNV protein (see page 76, lines 17-23). One would have been motivated to package the polypeptide of Chang into a kit in order to facilitate its sale, ease-of-use, transportation and storage as an ELISA reagent. One would have had a reasonable expectation of success that packaging of the WNV polypeptide into a kit would have been successful as it is routine in the art to package reagents for assays, evidenced by Degroot. Therefore, the embodiment would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

12. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, Art Unit 1648